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DOCKET NO.: P0738.70001US00

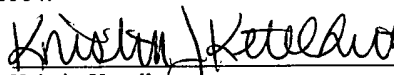
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Richard T. Lee, et al.  
Serial No.: 09/934,249  
Confirmation No.: 6506  
Filed: August 21, 2001  
For: DIAGNOSIS AND TREATMENT OF CARDIOVASCULAR  
CONDITIONS  
Examiner: Zachariah Lucas  
Art Unit: 1648

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to **MAIL STOP Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 27<sup>th</sup> day of August, 2004.

  
\_\_\_\_\_  
Kristin Ketelhut

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**MAIL STOP AMENDMENT**

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Copy of Invitation to Pay Additional Fees
- Copy of International Search Report
- Return Receipt Postcard

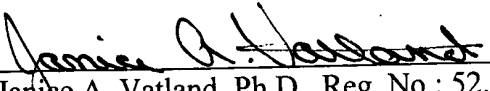
If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

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Docket No.: P0738.70001US00  
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A check in the amount of \$180.00 is enclosed to cover the Information Disclosure Statement filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Richard T. Lee, et al., Applicant*

By:

  
Janice A. Vatland, Ph.D., Reg. No.: 52,318  
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Telephone: (617) 646-8000

Docket No.: P0738.70001US00  
Date: August 27, 2004  
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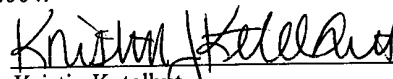
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Kristin Ketelhut

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**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

08/31/2004 SSANDARA 00000016 09934249

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Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the enclosed search report(s) or other communication(s) from corresponding International or Foreign National Application(s).

<u>Docket No.</u>	<u>Serial No.</u>	<u>Date of Mailing</u>	<u>Type of Communication</u>
<b>P0738.70001WO00</b>	<b>PCT/US01/26089</b>	<b>September 20, 2002</b>	<b>Invitation to Pay Additional Fees</b>
<b>P0738.70001WO00</b>	<b>PCT/US01/26089</b>	<b>December 5, 2002</b>	<b>International Search Report</b>

Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

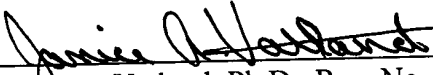
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

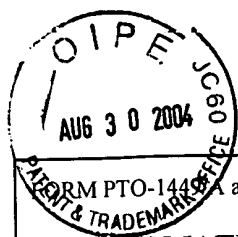
Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Richard T. Lee et al., Applicant*

By:   
Janice A. Vatland, Ph.D., Reg. No. 52,318  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
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FORM PTO-1449A and B (Modified) <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		APPLICATION NO.: 09/934,249	ATTY. DOCKET NO.: P0738.70001US00
		FILING DATE: August 21, 2001	CONFIRMATION NO.: 6506
		APPLICANT: Richard T. Lee et al.	
		GROUP ART UNIT: 1648	EXAMINER: Zachariah Lucas
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#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	5,217,899		Shapiro, et al.	06/08/1993

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

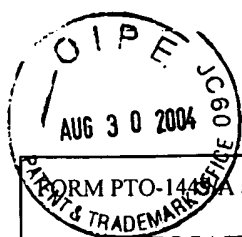
Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	C8	Arstall et al, "Human Ventricular Myocytes <i>in vitro</i> Exhibit Both Early and Delayed Preconditioning Responses to Simulated Ischemia," J Mol Cell Cardiol, Vol. 30, pp. 1019-25 (1998)		
	C9	Barbee et al, "Strain measurements in cultured vascular smooth muscle cells subjected to mechanical deformation," Ann Biomed Eng 1994 22(1): 14-22		
	C10	Carballo et al, "Bone Marrow Transplantation Reproduces the Tristetraprolin-Deficiency Syndrome in Recombination Activating Gene-2 (-/-) Mice," J Clin Invest, Vol. 100, No. 5, pp. 986-95 (1997)		
	C11	Chen et al., "Isolation and characterization of a novel cDNA from HL-60 cells treated with 1,25-hydroxyvitamin D-3," Biochim Biophys Acta 1219(1) 26-32, 1994		
	C12	Cheng, et al. "Mechanical Strain Tightly Controls Fibroblast Growth Factor-2 Release From Cultured Human Vascular Smooth Muscle Cells," Circ. Res. 1997; 80: 28-36.		
	C13	Cortes et al, "BTG Gene Expression in the p53-Dependent and -Independent Cellular Response to DNA Damage," Molecular Carcinogenesis, Vol. 27, pp. 57-64 (2000)		
	C14	Geisterfer-Lowrance et al., "A mouse model of familial hypertrophic cardiomyopathy," Science 1996 272: 731-734		
	C15	Haley et al, "Overexpression of Eotaxin and the CCR3 Receptor in Human Atherosclerosis: using genomic technology to identify a potential novel pathway of vascular inflammation," Circulation, Vol. 102, pp. 2185-2189 (2000)		
	C16	Hamada et al, "Stretch Activates Jun N-terminal Kinase/Stress-activated Protein Kinase in Vascular Smooth Muscle Cells through Mechanisms Involving Autocrine ATP Stimulation of Purinoceptors," J. Biol. Chem. Vol. 273, No. 11, pp. 6334-6340 (1998)		
	C17	Johnson et al, "Similar but distinct effects of the tristetraprolin/TIS11 immediate-early proteins on cell survival," Oncogene, Vol. 19, pp. 1657-1664 (2000)		
	C18	Karas et al, "Human vascular smooth muscle cells contain functional estrogen receptor," Circulation 1994 89: 1943-50		
	C19	Kaye et al, "Role of Transiently Altered Sarcolemmal Membrane Permeability and Basic Fibroblast Growth Factor Release in the Hypertrophic Response of Adult Rat Ventricular Myocytes to Increased Mechanical Activity In Vitro," J Clin Invest., Vol. 97, No. 2, pp. 281-91 (1996)		
	C20	Kobayashi et al, "Regulation of a Novel Immediate Early Response Gene, IEX-1, in Keratinocytes by 1 $\alpha$ , 25-Dihydroxyvitamin D <sub>3</sub> ," Biochem Biophys Res Commun., Vol. 251, pp. 868-73 (1998)		



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Sheet	2	of	3				

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C21	Kondratyev et al, "Identification and characterization of a radiation-inducible glycosylated human early-response gene," <i>Cancer Res</i> 1996 56(7):1498-502	
	C22	Kumar et al, "A Novel Immediate Early Response Gene, IEX-1, Is Induced by Ultraviolet Radiation in Human Keratinocytes," <i>Biochem Biophys Res Commun.</i> , Vol. 253, pp. 336-41 (1998)	
	C23	Lai et al, "Evidence that Tristetraprolin Binds to AU-Rich Elements and Promotes the Deadenylation and Destabilization of Tumor Necrosis Factor Alpha mRNA," <i>Mol Cell Biol</i> Vol. 19, No. 6, pp. 4311-23 (1999)	
	C24	Laufs et al. "Neuroprotection mediated by changes in the endothelial actin cytoskeleton" <i>J. Clin. Invest.</i> , Vol. 106, No. 1, pp. 15-24 (2000)	
	C25	Lee et al, "An equibiaxial strain system for cultured cells," <i>Am J Physiol.</i> , pp. C1400-8 (1996)	
	C26	Nie et al, " <i>ERF-2</i> , the human homologue of the murine <i>Tis11d</i> early response gene," <i>Gene</i> Vol. 152, pp. 285-6 (1995)	
	C27	Nishiyama et al. "Identification of Thioredoxin-binding Protein-2/Vitamin D <sub>3</sub> Up-regulated Protein 1 as a Negative Regulator of Thioredoxin Function and Expression". <i>Journal of Biological Chemistry</i> Vol. 274, No. 31, pp. 21645-21650 (1999)	
	C28	Saitoh et al, "Mammalian thioredoxin is a direct inhibitor of apoptosis signal-regulating kinase (ASK) 1," <i>EMBO Journal</i> , Vol. 17, No. 9, pp. 2596-2606 (1998)	
	C29	Schafer et al, "The putative apoptosis inhibitor IEX-1L is a mutant nonspliced variant of p22 <sup>PRG1/IEX-1</sup> and is not expressed <i>in vivo</i> ," <i>Biochem Biophys Res Commun</i> 1999, 262(1):139-45	
	C30	Schafer et al, "Human PACAP response 1 gene (p22/PRG1): proliferation-associated expression in pancreatic carcinoma cells," <i>Pancreas</i> 1999 18(4): 378-84	
	C31	Schafer et al, "The promoter of human p22/PACAP response gene 1 (PRG1) contains functional binding sites for the p53 tumor suppressor and for NFκB," <i>FEBS Lett</i> 1998 436(2): 139-43	
	C32	Schafer et al, "PRG1: A novel early response gene transcriptionally induced by pituitary adenylate cyclase activating polypeptide in a pancreatic carcinoma cell line," <i>Cancer Res.</i> 1996 56: 2641-2648	
	C33	Segev et al, "Müllerian Inhibiting Substance Inhibits Breast Cancer Cell Growth through an NFκB-mediated Pathway," <i>J Biol Chem.</i> , Vol. 275, No. 37, pp. 28371-28379 (2000)	
	C34	Tagaki et al, "Expression of thioredoxin is enhanced in atherosclerotic plaques and during neointima formation in rat arteries," <i>Lab Invest</i> 1998, 78:957-96	
	C35	Taylor et al, "A pathogenic role for TNFα in the syndrome of cachexia, arthritis, and autoimmunity resulting from tristetraprolin (TTP) deficiency," <i>Immunity</i> 1996 May 4(5) 445-54	
	C36	Topper et al, "Vascular <i>MADs</i> : Two novel <i>MAD</i> -related genes selectively inducible by flow in human vascular endothelium," <i>PNAS</i> , Vol. 94, pp. 9314-9319 (1997)	
	C37	Wu et al, "IEX-1L, an apoptosis inhibitor involved in NF-κB-mediated cell survival," <i>Science</i> 1998 281(5379):998-1001	
	C38	Yang et al, "Expression of a vitamin D-regulated gene (VDUP-1) in untreated and MNU-treated rat mammary tissue," <i>Breast Cancer Res Treat</i> , Vol. 48, pp. 33-44 (1998)	
	C39	NCBI Accession No. AI761441	
	C40	NCBI Accession No. AL12193	
	C41	NCBI Accession No. AI594390	
	C42	NCBI Accession No. NM_004338	
	C43	NCBI Accession No. AQ177461	
	C44	NCBI Accession No. AL035541	
	C45	NCBI Accession No. X67644	
	C46	NCBI Accession No. AF173681	
	C47	NCBI Accession No. X77585	
	C48	NCBI Accession No. P46694	
	C49	NCBI Accession No. U72649	



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	C50	NCBI Accession No. M92843	
	C51	NCBI Accession No. S73591 (VDUP1/mRNA)	
	C52	NCBI Accession No. S81914	
	C53	NCBI Accession No. AF083421	
	C54	NCBI Accession No. AF071596	
	C55	NCBI Accession No. AF039067	
	C56	NCBI Accession No. Y14551	
	C57	NCBI Accession No. NP_003888	
	C58	NCBI Accession No. P46695	
	C59	NCBI Accession No. NM_006472	
	C60	NCBI Accession No. NP_006463	
	C61	NCBI Accession No. H28363	
	C62	NCBI Accession No. H28387	
	C63	NCBI Accession No. S73591 (MG068 homolog)	

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]